Claims

What is claimed is:

1. A method for the preparation of a liquid stable glycosylated hemoglobin (Hemoglobin A1C) control and calibrant, the method comprising:

a first step of separating human red blood cells (RBC, Erythrocytes) from anti-coagulated blood;

a second step of washing the human red blood cells 3 times with an equal volume of physiological saline, including after each washing centrifuging the red blood cells to pack them down, and aspirating and discarding a resulting supernatant and white blood cells;

a third step of lysing the packed red blood cells by adding a quantity of purified water to produce a cell/water mixture;

a fourth step of mixing and freezing the cell/water mixture to produce frozen lysed red blood cells;

a fifth step of defrosting the frozen lysed red blood cells to produce a hemolysate;

a sixth step of centrifuging the hemolysate to produce a resulting supernatant,

a seventh step of filtering and saving the supernatant;

an eighth step of heating the supernatant to ensure that a labile fraction of hemoglobin A1c is low;

a ninth step of diafiltering the hemolysate to remove all the small molecules, especially glucose; and

a tenth step of adjusting the hemolysate so that a final hemoglobin concentration is within specified limits.

2. The method of claim 1 further comprising an eleventh step of adding a quantity of a cyanide salt.

3. The method of claim 1 further comprising an eleventh step of adding a quantity of carbon monoxide to ensure the physical appearance of the product.

4. The method of claim 1 further comprising adding a quantity of appropriated preservatives during the processing to prevent microbial contamination and growth.

5. The method of claim 1 wherein the third step further comprises adding a quantity of a cyanide salt to the solution to ensure that a concentration of methemoglobin is kept to a minimum.

6. The method of claim 1 wherein the ninth step further comprises adding glucose to the hemolysate prior to the diafiltering and placing the glucose and hemolysate at 37°C to allow glycosylation to proceed until a concentration of glycosylated hemoglobin has reached a target concentration; and

an eleventh step of incubating the hemolysate at 37°C to ensure that the labile fraction of A1c is low.

7. The method of claim 6 a twelfth step of adding a quantity of a cyanide salt.

8. The method of claim 6 further comprising a twelfth step of adding a quantity of carbon monoxide to ensure the physical appearance of the product.

9. The method of claim 6 further comprising adding a quantity of appropriated preservatives during the processing to prevent microbial contamination and growth.